

THIRTY-EIGHTH MEETING

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

January 26, 2001

**National Institutes of Health
Bethesda, Maryland**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened for its thirty-eighth meeting on January 26, 2001, in Conference Room C, Neurosciences Center, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Open: January 26, 2001: 8:30 a.m. to 12:00 p.m., for the review and discussion of program development, needs and policy; and

Closed: January 26, 2001: 12:00 p.m. to 1:40 p.m. for review of individual grant applications.

Council members present:¹

Dr. Rita S. Berndt
Dr. Gail D. Burd
Dr. Bernard Cohen
Dr. David P. Corey
Ms. Rebecca Dresser
Dr. Judy R. Dubno
Dr. Beverly Emanuel
Dr. Bernard Harris
Dr. Ronald R. Hoy

Dr. Nicolas Linares-Orama
Mr. John Madison
Dr. Miriam H. Meisler
Ms. Donna L. Sorkin
Ms. Virginia W. Stern
Dr. Orlando Taylor
Dr. Ingo Titze
Dr. Gregory T. Wolf

Council member absent:

Dr. Jacqueline E. Jones

¹For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

Ex-Officio Members present:

Dr. Lucille B. Beck

Ex-Officio Members absent:

Dr. John R. Franks

Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

I. Call To Order and Opening Remarks Dr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed his appreciation to all Council members for their service and advice to the Institute. He also expressed his gratitude to Jeannie Combs for her management of the NIDCD Advisory Council's Homepage, which has become the primary source of information related to the meeting.

II. Council Procedures Dr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members avoiding conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be open to the public during the morning session, but would be closed for consideration of grant applications during the afternoon.

Consideration of Minutes from the Meeting of September 15, 2000

Dr. Battey called members' attention to the Minutes of the Council's meeting of September 15, 2000. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2002 have been established. A list of these meetings was distributed to the Council members. The next meeting of Council is scheduled for Thursday, May 24, 2001 on the NIH campus, Bethesda, Maryland.

III. Report of the Director, NIDCD Dr. Battey

Budget Considerations

In his discussion of the Institute's budget, Dr. Battey demonstrated how the nearly \$55.5 million available for new and competing research project grants has been allocated in FY2001. First, 8.2 million is required for fiscal year programmatic requirements. The remaining \$47.2 million is then divided equally among the three Council meetings, yielding \$15.5 million for the January Council. Twenty percent of this (\$3.2 million) will be designated for High Program Priority. This leaves approximately \$12.6 million available for the initial payline, which should allow funding of applications to the 25th percentile. A copy of the slides Dr. Battey used for his budget presentation is included in these Minutes as Appendix 3.

New Training/Career Development Initiatives

Dr. Battey discussed the new individual predoctoral fellowship award (F31) to support dissertation research. The first round of applications for this new program were received and reviewed during the fall of 2000. A major NIDCD goal for this program is to expedite the review and award of applications, with a goal of four months from receipt to award. In order also to expedite the review of postdoctoral fellowships (F32), both of these fellowship mechanisms are being reviewed in the Scientific Review Branch of NIDCD.

Regarding career development awards, Dr. Battey presented plans for expanded support for salary and research support on K08 and K23 awards. Plans also are being formulated for a K22 Transition Award to facilitate the movement of postdoctoral fellows into their first faculty position. Finally, based upon recent congressional authorization, the NIH is developing a Loan Repayment Program for beginning investigators pursuing clinical and pediatric research.

Collaboration between the University of Maryland and the NIDCD

Dr. Battey discussed a new collaboration between the University of Maryland and the NIDCD. The Center for Comparative and Evolutionary Biology of Hearing at the University of Maryland will work closely with the Division of Intramural Research, NIDCD. Dr. Battey stated that graduate students are the "glue" for collaborations between labs at both locations. This collaboration will present valuable teaching opportunities for NIDCD, and should be very beneficial in development of future intramural principal investigators and postdoctoral fellows.

IV. Report of the Director, Division of Extramural Research Dr. Robert Dobie

New Staff

Dr. Dobie introduced Dr. Lana Shekim and Ms. Sara Stone, both new employees of the Division. Dr. Shekim will serve as a Program Administrator in the Voice, Speech and Language Program of the Scientific Programs Branch. Ms. Stone serves as the Grants Management Officer, a position formerly held by Ms. Sharon Hunt.

Dr. Dobie thanked Ms. Sherry Dabney for serving as Acting Grants Management Officer in the period immediately following Ms. Hunt's retirement.

Changing P50 Mechanism:

Dr. Dobie introduced Dr. Lynn Luethke, who discussed changes in the Multiple Project Center program. Following recommendations from the Work Group on Single and Multiple Project Grants, the NIDCD made substantive revisions to their multiple project (P50/P01) programs in 1999, eliminating the P01, changing the P50 and adding the Core Center (P30) grant mechanism. After experience with these programs, the NIDCD has made additional changes to the way it will support multiple project center (P50) grants. In summary, the main changes include: 1) the requirement that the research conducted on a P50 be clinical in nature, and 2) the removal of the requirement that subprojects must be interdependent.

The NIDCD will now restrict grants to the support of clinical research (i.e., research involving individuals with disorders or data/tissues derived from individuals with disorders, to study a disorder of human communication; examples of such research include, but are not limited to, studies of the prevention, pathogenesis, pathophysiology, diagnosis, treatment, management or epidemiology of a disease or disorder of hearing, balance, smell, taste, voice, speech, or language). Non-human research is precluded on an NIDCD P50 grant and humans without communication disorders may participate in the research only when normal controls are needed. The four essential criteria for the new P50 are:

1. The research to be conducted must be clinical (see above for definition).
2. The P50 must have a well-defined central unifying theme consisting of three or more subprojects with supporting cores as appropriate.
3. Each subproject must be unambiguously related to the central unifying theme.
4. The P50 must be multidisciplinary.

The NIDCD believes that most research within its mission areas can be best accomplished via the investigator-initiated individual research grant (R01) and the research core center grant (P30) mechanisms. There are special circumstances in clinical research, however, that warrant the use of the P50 mechanism.

Policy on Responsible Conduct of Research:

Dr. Dobie discussed the final PHS Policy on Instruction in the Responsible Conduct of Research (RCR), which was adopted and published by the Office of Research Integrity on December 1, 2000. It is the policy of the PHS that research staff at extramural institutions shall complete a basic program of instruction in the responsible conduct of research. Research staff who are working on the PHS-supported project at entities other than the institution that received the PHS research grant, cooperative agreement, or contract, are also covered by the policy. The institution may make reasonable determinations as to which research staff fall within the policy. The policy pertains to all research, including animal, human, and basic research, or research training, conducted with grant, contract, or cooperative agreement support from any agency, or office, of the PHS.

The PHS also recommends, but does not require, that the institution consider the need for providing RCR instruction to (1) non PHS-supported research staff at the institution, including those supported by institutional, private, and other governmental sources of support and (2) departmental and sponsored research/administrative staff and other support staff, with instruction relevant to their jobs and roles in the research enterprise (as determined by the institution). This policy does not limit the authority of the institution to expand the policy's scope or to impose broader requirements for RCR education.

Further details about this policy may be found at the Office of Research Integrity's website <http://www.ori.hhs.gov/html/programs/finalpolicy.asp>.

[Executive Secretary Note: The following statement is an excerpt from the NIH Guide NOTICE: NOT-OD-01-020, February 22, 2001. "Consistent with the President's January 20, 2001, Regulatory Review Plan, on behalf of PHS, ORI hereby suspends implementation of the "PHS Policy on Instruction in the Responsible Conduct of Research" to permit additional review both of the substance of the policy and the process for adoption."]

Review of Implementation of NIH Policy

On a biennial basis, the advisory councils of the NIH Institutes are asked by the Office of Research on Women's Health to review the procedures used by their respective institutes to implement the 1994 NIH guidelines for the inclusion of women and minorities in clinical research.

The previous review was performed in 1999. Dr. Dobie told the Council that it is once again time to review the NIDCD implementation of, and to certify NIDCD compliance with, the 1994 Guidelines. A copy of the report and its appendices will be sent to each Council member when it is available in early February.

[Executive Secretary Note: The report on inclusion of women and minorities was mailed to Council members on February 2, 2001. The report was endorsed by the Council via mail ballot.]

An Update on the Review of the Scientific Review Process in NIDCD

Dr. Dobie reported that the internal review of peer review procedures within the Scientific Review Branch of NIDCD is proceeding and several recommendations have been developed. It is recommended that: applications for clinical trial grants continue to be reviewed collaboratively at the NHLBI's Clinical Trials Review Committee, the Institute's Research Core Center (P30) and Clinical Research Center (P50) grant applications be reviewed by separate review panels, and that the P50s should remain in the Communication Disorders Review Committee (CDRC). In addition, the group believes that there is insufficient workload to permit defining review groups by mission areas and that Small Grants (R03) are best reviewed in Special Emphasis Panels, based on the volume of work and the ability to use this activity as a training ground for newer reviewers. One issue that will be explored during the next year is the potential for CDRC subcommittees for reviewing specific activities and/or providing flexibility in dealing with conflict issues.

V. Scientific Presentation: Dr. Dennis Drayna

Dr. Battey introduced Dr. Dennis Drayna, a Special Expert in the Laboratory of Molecular Biology, Division of Intramural Research, NIDCD. Dr. Drayna discussed his lab's genetic studies of human communication disorders. Following is an abstract of Dr. Drayna's presentation:

"Genetic Studies of Human Communication Disorders"

Our group focuses on genetic aspects of communication disorders in humans, in the areas of speech and language, aspects of hearing, and human chemosensory deficits. In the area of speech and language, we have been engaged in a genetic linkage study of stuttering, attempting to identify the chromosomal location of genes which predispose individuals to this disorder. Our study is designed to address the numerous epidemiological characteristics of stuttering which have complicated genetic approaches in the past. Our approach is focused on affected individuals with persistent stuttering. We have assembled a group of over 100 families from the general population which display multiple cases of persistent stuttering. We've obtained DNA samples and speech diagnosis on the members of these families and have tested roughly 400 genetic markers in these individuals. Non-parametric analysis has identified a single location that gives strong statistical evidence for the presence of a causative gene for this disorder. Current studies are refining the location of this gene with the goal of isolating it and studying its function.

VI. Operating Procedures Dr. Jordan

Dr. Jordan called Council's attention to a copy of the Council Operating Procedures which had been provided to each member prior to the meeting. The Council Operating Procedures state those actions which Council empowers staff to take without specific prior Council approval. He opened discussion of this document by explaining that it is the

Institute's procedure to review the Council Operating Procedures annually at the January Council. There are no recommended changes to the document this year, so this version is identical to the version approved last January. The document was endorsed unanimously for the current year, and is included in these minutes as Appendix 4.

VII. Open Discussion with the Director Dr. Battey

Dr. Battey engaged the Council members in open discussion. Members discussed a number of topics and were interested in: 1) developing a better understanding of the relationship between the Institute's strategic plan goals and its impact on grants eventually funded, 2) receiving additional information on the Institute's plans and accomplishments in information dissemination, 3) receiving additional information on the Institute's contract portfolio, and 4) receiving additional detail about the Institute's fiscal year 2001 implementation plans for new initiatives. In addition, a large part of the open discussion revolved around the importance of translational research and the potential ways to nurture/support such research. Council members recommended that the NIDCD consider the best approaches to ensure adequate support of this important phase, which leads to the ultimate payoff, effective clinical application.

CLOSED SESSION

VIII. Council Consideration of Pending Applications

The Council gave special attention to applications from foreign institutions and to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or women/minority/children representation in study populations as identified by the initial review groups.

A. Research Project Grant Awards

1. Consideration of Applications: On the Council's agenda was a total of 123 research grant applications; 86 applications had primary assignment to NIDCD, in the amount of \$22.8 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to applications scoring through the 25th percentile.

B. Special Programs Actions

1. Small Grants (R03): The Council recommended support for eleven applications.
2. Small Business Technology Transfer (STTR): The Council recommended support for one Phase II (R42) application.

3. Small Business Innovation Research Awards (SBIR). The Council recommended support for two Phase I (R43) and two Phase II (R44) applications.
4. High Impact Research: Feasibility Studies (PAR-00-075) (R21): The Council recommended support for six applications.
5. Mutagenesis Screens/Phenotyping Tools for Zebrafish (RFA-HD00-004) (R01): The Council recommended support for one application.

C. Training Programs

1. Institutional National Research Service Awards (T32): The Council recommended support for three applications.
2. Jointly Sponsored NIH Predoctoral Training Program in the Neurosciences (PAR-00-037): The Council recommended co-funding support for one application

D. Career Development Programs

1. Mentored Clinical Scientist Development Award (K08): The Council recommended support for three applications.
2. Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support for two applications.

IX. Adjournment: The meeting was adjourned at 1:40 p.m. on January 26, 2001.

X. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.²

Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

James F. Battey, Jr., M.D., Ph.D.
Chairman
National Deafness and Other Communication
Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders

Jeannie Combs
Council Assistant

² These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

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Appendix 1

Roster

National Deafness and Other Communication Disorders Advisory Council

Chairperson

Battey, James F., Jr., M.D., Ph.D.

Director

National Institute on Deafness and Other Communication Disorders

Bethesda, Maryland 20892

BERNDT, Rita S., Ph.D. Professor Department of Neurology University of Maryland School of Medicine Baltimore, Maryland	2002	DRESSER, Rebecca S., J.D. Professor, School of Law and Program for the Humanities in Medicine Washington University School of Law St. Louis, Missouri	2001
BURD, Gail D., Ph.D. Professor and Associate Department Head Molecular and Cellular Biology University of Arizona Tucson, Arizona	2003	DUBNO, Judy R., Ph.D. Professor Department of Otolaryngology- Head and Neck Surgery Medical University of South Carolina Charleston, SC	2003
COHEN, Bernard, M.D. Morris B. Bender Professor of Neurology Department of Neurology Mount Sinai School of Medicine City University of New York New York, New York	2002	EMANUEL, Beverly S., Ph.D. The Charles E.H.Upham Professor of Pediatrics University of Pennsylvania School of Medicine; Chief, Division of Human Genetics and Molecular Biology The Children's Hospital of Philadelphia Philadelphia, PA	2004
COREY, David P., Ph.D. Professor of Neurobiology Harvard Medical School Neurobiologist, Department of Neurobiology Massachusetts General Hospital Boston, Massachusetts	2001	HARRIS, Bernard A., Jr., M.D. Vice President Microgravity and Life Science SPACEHAB, Inc. Houston, Texas	2002
		HOY, Ronald R., Ph.D. Professor Section of Neurobiology and Behavior Cornell University Ithaca, New York	2003

JONES, Jacqueline E., M.D. Associate Professor of Clinical Otolaryngology Cornell University Medical College New York, New York	2002	WOLF, Gregory T., M.D. Chair, Department of Otolaryngology- Head and Neck Surgery University of Michigan Medical Center Ann Arbor, Michigan	2001
LINARES-ORAMA, Nicolas, Ph.D. Professor Office for Research and Development College of Health Professions University of Puerto Rico Medical Sciences Campus San Juan, Puerto Rico	2004	<u>Ex-Officio Members:</u> BECK, Lucille B., Ph.D. Director Audiology and Speech Pathology Service Department of Veterans Affairs Washington, D.C.	
MADISON, John P., Ed.D. Associate Professor Department of English National Technical Institute for the Deaf Rochester, NY	2004	FRANKS, John R., Ph.D. Chief, Bioacoustics and Occupational Vibration Section Physical Agent Effects Branch Division of Biomedical and Behavioral Science National Institute for Occupational Safety and Health Cincinnati, Ohio	
MEISLER, Miriam H., Ph.D. Professor Human Genetics Department School of Medicine University of Michigan Ann Arbor, Michigan	2003	HOFFER, Michael E., M.D. Co-Director Department of Defense Spatial Orientation Center Department of Otolaryngology Naval Medical Center San Diego, California	
SORKIN, Donna L. Executive Director Alexander Graham Bell Association for the Deaf and Hard of Hearing Washington, DC	2002	SHALALA, Donna E., Ph.D. Secretary Department of Health and Human Services Washington, D.C.	
STERN, Virginia W. Director, Project on Science, Technology and Disability American Association for the Advancement of Science Washington, D.C.	2001	KIRSCHSTEIN, Ruth L., M.D. Acting Director National Institutes of Health Bethesda, Maryland	
TAYLOR, Orlando L., Ph.D. Dean Graduate School of Arts & Sciences Howard University Washington, D.C.	2001	<u>EXECUTIVE SECRETARY</u>	
TITZE, Ingo R., Ph.D. Distinguished Professor Department of Speech Pathology and Audiology University of Iowa Iowa City, IA	2004	JORDAN, Craig A., Ph.D. Executive Secretary Division of Extramural Research, NIDCD Bethesda, Maryland	

Appendix 2

ATTENDANCE LIST

Other than Council members, attendees at the January 2001 Council meeting included:

NIDCD Staff:

Office of the Director

Luecke, Donald H., M.D., Deputy Director
Phillips, Isabelle, Secretary
Lopez, Joyce, Program Specialist

Office of Health Communication and Public Liaison

Allen, Marin, Chief
LaBella, Shirley

Office of Administration

Kerr, W. David, Executive Officer

Financial Management Branch

Sparks, Patience, Budget Officer
Kniel, Sylvia, Budget Analyst

Information Systems Management Branch

Jones, Jackie, Chief

Science Policy and Legislation Branch

Smith, Mary, Acting Chief
Wong, Baldwin, Program Analyst

Equal Employment Opportunities Branch

Johnson-Graham, Kay, EEO Officer
Grant, Shelma, EEO Specialist

Division of Extramural Research

Dobie, Robert A., M.D., Director
Combs, Jeannie, Program Analyst
DaSilva, Maria, Program Assistant
Holmes, Debbie, Secretary
Stephenson, Nanette, Program Assistant

Grants Management Branch

Stone, Sara, Chief
Chicchirichi, David, Grants Management Specialist
Dabney, Sherry, Grants Management Officer

McNamara, Castilla, Grants Management Specialist
Ranney, Meigs, Grants Management Officer

Scientific Programs Branch

Cooper, Judith, Ph.D., Chief; and Program Director, Language
Davis, Barry, Ph.D., Program Director, Taste/Gustation
Shekim, Lana, Ph.D., Program Director, Voice, Speech and Language

Hearing and Balance/Vestibular Section

Donahue, Amy, Chief; and Program Director, Hearing
Freeman, Nancy, Ph.D., Program Director, Hearing
Johnson, Thomas, Ph.D., Program Director, Hearing
Luethke, Lynn, Ph.D., Program Director, Hearing
Sklare, Daniel A., Ph.D., Program Director, Balance/Vestibular

Clinical Trials, Epidemiology and Biostatistics Section

Gulya, Julie, M.D., Chief, Program Director, Clinical Trials
Hoffman, Howard, Program Director for
Epidemiology & Biostatistics
Jelen, Janet, Computer Specialist
Chiu, May, Program Analyst

Scientific Review Branch

Jordan, Craig A., Ph.D., Chief
Oaks, Stanley C., Ph.D., Scientific Review Administrator
Stick, Melissa J., Ph.D., M.P.H., Scientific Review Administrator

Division of Intramural Research

Drayna, Dennis, Special Expert, LMB
Chadwick, Richard, Chief, Section on Auditory Mechanics, LCB

Center for Scientific Review, NIH

Kimm, Joseph, Ph.D., Scientific Review Administrator
Kenshalo, Daniel, Ph.D., Scientific Review Administrator
Dimitrov, Mariana, Ph.D., Scientific Review Administrator
Melchior, Christine, Ph.D., Scientific Review Administrator

Others

Moss, Sharon, Ph.D., American Speech and Hearing Association
Stone, Alec, Ph.D., Deafness Research Foundation
Dunlap, T.J., JTxCo, Texas
Dunlap, J.R., JTxCo, Texas
Nuss, Mary, Deputy Committee Management Officer, NIAID

Appendix 3

NIDCD Director's Report Slides

As Presented By
James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting

January 26, 2000

**National Institute on Deafness and Other Communication Disorders
Budget Mechanism**

(Dollars in thousands)

	FY 2001 <u>Appropriation</u>	Percent of <u>Total</u>
Research Projects Grants	\$218,248	72.5%
Research Centers	16,900	5.6%
Other Research	<u>6,609</u>	<u>2.3%</u>
Total, Res. Grants	241,757	80.4%
Individual Training	2,826	
Institutional Training	<u>7,032</u>	
Total, Training	9,858	3.3%
R&D Contracts	10,526	3.7%
Intramural Research	26,470	8.6%
Research Mgmt. & Support	<u>11,807</u>	4.0%
 TOTAL	 300,418	

National Institute on Deafness and Other Communication Disorders

**January 2001 Council
Competing Research Project Grants
(Dollars in thousands)**

\$ 55,482

-8,213 Programmatic funding requirements

47,269

/3

15,576 Identified for January Council

x.20

3,151 Available for HPP

**\$12,605 Available for initial payline
to the 25.0 percentile**

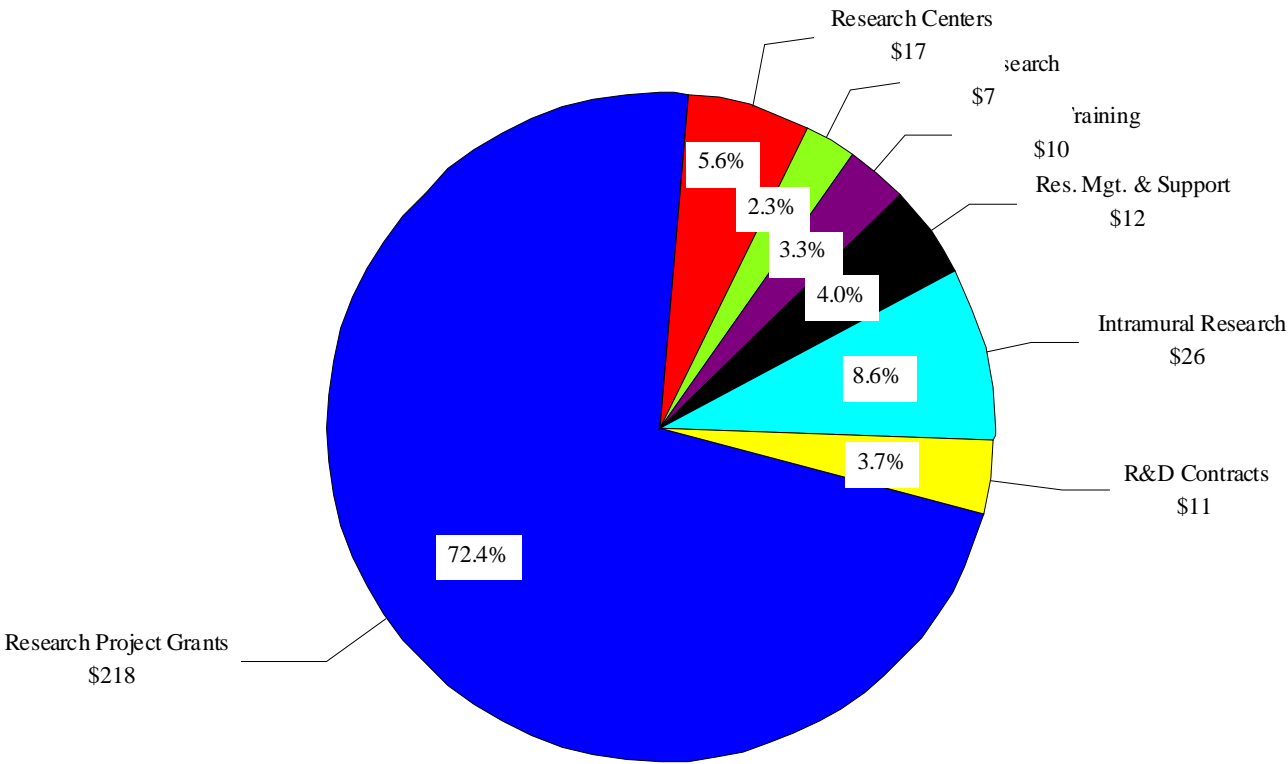
**National Institute on Deafness and Other Communication Disorders
Research Project Grants
(Dollars in thousands)**

**FY 2001
Appropriation**

	<u>No.</u>	<u>Amount</u>
Noncompeting	551	\$154,831
Admin. Supp.	(30)	1,100
<u>Competing</u>	<u>200</u>	<u>55,482</u>
Subtotal, RPGs	751	211,413
SBIR/STTR	<u>32</u>	<u>6,835</u>
Total, RPGs	783	218,248

**National Institutes of Health
National Institute on Deafness and Other Communication Disorders**

**FY 2001 Appropriation
(Dollars in Millions)**



Appendix 4

NIDCD Advisory Council Operating Procedures

(As endorsed by Council January 26, 2001)

The Institute staff may take the following actions without Council review. All actions shall be documented and presented to the Council for its information at the first appropriate opportunity.

1. Approval of New Principal Investigator or Program Director

Give approval of a new principal investigator or program director to continue an active grant at the grantee institution.

2. Replacement of Research Grant for Investigator Who Moves to a New Institution

Make research grant awards equal to the remaining committed support for continuing work under the same principal investigator when that principal investigator moves from one institution to another. This provision will not be automatic, however. Staff may approve less than the remaining committed support and will in all cases carefully document for the file the rationale for the action.

3. Awards for Orderly Termination

Make appropriate awards for orderly termination of competing continuation applications which were not recommended for further consideration, or which received a score too low for payment; this procedure is to be used in those cases where sudden termination of the grant would cause a serious loss of scientific material or impose a hardship to already employed personnel. In such cases, (1) the grant usually should be for a period not to exceed twelve months, (2) careful review should be given to needs for salaries and consumable supplies, (3) usually no funds would be provided for additional equipment or travel, and (4) in the case of training grants, support would be provided for those trainees already in the program.

4. Awards for Interim Period Due to a Deferral

Make awards in an appropriate amount and for an appropriate interim period of time when a recommendation of deferral on a competing continuation application results in a loss of continuity of the active research or training program. Careful review should be given to the needs for personnel and consumable supplies; however, usually no funds would be provided for equipment or travel.

5. Supplemental Support to Existing Research and Training Awards

Provide additional support up to \$100,000 in direct costs per year to carry out the scientific, administrative and fiscal intent of the research or training award. The additional support may be necessary to: a) make NIH-wide supplemental awards for under-represented minorities, individuals reentering science, or individuals with disabilities; b) provide administrative increases; c) cover unanticipated costs; or d) ensure effective operation of the recommended program. Increases greater than \$100,000 will be presented to the NDCD Advisory Council for approval before an award is made.

Institute staff may take the following actions without subsequent reporting to the Council.

1. Continuation of Grant in Temporary Absence of Principal Investigator or Program Director.

Give approval for continuation of grants in the temporary absence of the principal investigator or program director.

2. Extension of Project Period Dates

Take necessary action on extensions of project period end dates without additional funds.

3. Scientific Evaluation Grants

Take final action in awarding supplements to the chairpersons of the NIDCD research and training review committees in an amount necessary to carry out the functions of the committees.